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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,676

09/22/2003

Garth Boehm

224562

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65626 7590 04/17/2009
PATRICK J. HALLORAN, PH.D., J.D.
3141 MUIRFIELD ROAD
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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,676	Applicant(s) BOEHM, GARTH	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-47, 50-58, 61-69, 72-80 and 82-87 is/are rejected.
- 7) ☒ Claim(s) 48, 49, 59, 60, 70, 71 and 81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment and response filed 02/04/2008.

Regarding the restriction requirement, a typographical error was made and Group III should have been indicated as none-elected. Groups I and II will be examined.

The rejections under 35 USC 102(b) over Breder et al and Oshlack et al are withdrawn in view of applicant's showing of an ineffective date.

The following rejections are maintained in this action:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 39-47, 50-58, 61-69, 82-87 are are rejected under 35 U.S.C. 102(e) as being anticipated by Breder et al (US 2003/0157168)

Breder et al disclose an oral dosage form which comprises a sequestered opioid antagonist which is substantially not released when intact (see Abstract). Hydrophobic materials are disclosed for use in coating and sequestering the antagonists (see page 10, [0123]). In particular, cellulose polymers and acrylic polymers are set out at [0123] –[0127]. Other hydrophobic polymers suitable to coat the antagonist are listed at [0128]. Ph dependent or enteric coatings are disclosed at [0145] –[0157]. These include Eudragit polymers which have an ammonium content. Figure 2 shows that the applied coating substantially prevents release of the antagonist for up to 36 hrs. The reference discloses the same hydrophobic barrier polymers disclosed for the same art recognized purpose of sequestering antagonists, therefore the coating of the reference would inherently prevent release for the same 72 hrs as claimed herein, and is capable of preventing the same amount of that substance to be released. Capsules and tablets are set out as preferred embodiments at [0135]. Opioid agonists are listed at [0099 – 0101]. Opioid antagonists are listed at [0108 – 0110]. Beads coated with an opioid agonist , and opioid antagonist in non-releasable form are disclosed at [0164] and entail multiple subunits with releasable therapeutic with a coated (sequestered) antagonist in each. Subunits with either agonist or antagonist are set out at [0213]. A Hydrophilic core, with an aversive agent coating further coated with a hydrophobic agent is listed at [0166] – [0167]. The instant claims are anticipated by Breder et al.

Claims 39-47, 50-58, 61-69, 82-87 are rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al (US 2003/0064099).

Oshlack et al disclose an oral dosage form which comprises a sequestered opioid irritants and bittering agents which are substantially not released when intact (see Abstract). Hydrophobic materials are disclosed for use in coating and sequestering the antagonists. In particular, cellulose polymers and acrylic polymers are set out at [0605] –[0075]. Ph dependent or enteric coatings are disclosed at [0139] –[0141]. These include Eudragit polymers which have an ammonium content. The reference discloses the same hydrophobic barrier polymers disclosed for the same art recognized purpose of sequestering antagonists, therefore the coating of the reference would inherently prevent release for the same 72 hrs as claimed herein, and is capable of preventing the same amount of that substance to be released. Capsules and tablets are set out as preferred embodiments at [0077] - [0082]. Opioid agonists are listed at [0056 – 0063]. The aversive agents (irritants and bittering agents) are listed at [0044 – [0055]. Beads coated with an opioid agonist , and opioid antagonist in non-releasable form are disclosed at [0084] and entail multiple subunits with releasable therapeutic with a coated (sequestered) antagonist in each. Subunits with either agonist or antagonist are set out at this paragraph. A Hydrophilic core, with an aversive agent

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coating further coated with a hydrophobic agent is listed at [0086]. The instant claims are anticipated by Oshlack et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-17 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breder et al.

Breder et al disclose sequestering various aversive agents behind coatings of hydrophobic materials (see discussion of the disclosure above). While the specific coating pattern of the instant claims is not specifically disclosed by Breder et al, Breder et al does suggest multiple coating formulations with respect to the discussion of the figures. As such, those of ordinary skill at the time of invention would have found it well within their skill to apply any number of hydrophobic coatings and aversive agent layers including those of the instant claims with a reasonable expectation of discouraging opioid abuse. As such, the instant claims would have been obvious to one of ordinary skill in the pharmaceutical arts at the time of invention given the disclosure of Breder et al.

Response to Arguments

Applicant's arguments filed 02/04/2009 have been fully considered but they are not persuasive.

Applicant argues that Breder et al does not disclose a single pharmaceutical unit, but instead, separate beads comprising antagonist and agonist, respectively. However [0164] specifically refers to the hydrophobic coating as having controlled release properties. This is clearly referring the agonist release. Previous paragraphs cited in the rejection such as [0128] detail coating the antagonist with this hydrophobic coating. Paragraph 164 then specifically mentions that the antagonist is in non-releasable form. Further, the independent claims do not require the sequestering material to be a surfactant. For these reasons, the rejection under 35 USC 102(e) over Breder et al is maintained.

With regard to Oshlack et al, applicant argues that they do not believe the reference teaches a single pharmaceutical unit comprising an antagonist coated with a composition of an agonist. However, at [0084], Oshlack et al clearly state that the beads comprise an opioid analgesic (agonist) which is then coated with the aversive agent can be the antagonist. This rejection is maintained.

With regard to the rejection of the claims under 35 USC 103(a) over Breder et al, applicant cited case law , but makes no argument as to why the rejection lacks logical underpinnings when specific sections of the reference are cited. A proper response should also entail reasons why the holding of obviousness are not proper given the cited reference. As such, the rejection is maintained in this action.

The following is a new rejection of the claims made necessary by the amendment of 02/04/2009:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 72-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As written, claim 72 seems to say that the blocking agent is impermeable to the aversive agent (opioid antagonist) and a surfactant. However, the surfactant is the blocking agent. Clarification is requested.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 48, 49, 59, 60, 70, 71 and 81 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

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